No. 14-2071

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated

Plaintiffs – Appellants

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTHCARE & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEAL TH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; WALGREEN CO.; THE KROGER CO.; SAFEWAY INC.; ALBERTSON'S, LLC; HEB GROCERY COMPANY L. P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORTATORIES IRELAND LIMITED; WARNER CHILCOTT COMPANY; ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.

Defendants – Appellees

No. 15-1250

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; END PAYOR PLAINTIFFS; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOC. OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS' INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; A. F. OF L. BUILDING TRADES

WELFARE PLAN; NEW YORK HOTEL TRADES COUNCIL AND HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated

Plaintiffs – Appellants

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly; WALGREEN CO.; THE KROGER COMPANY; SAFEWAY INCORPORATED; ALBERTSON'S, LLC; HEB GROCERY COMPANY. L.P.

Plaintiffs

v.

WARNER CHILCOTT COMPANY, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.

Defendants – Appellees

On Appeal from the United States District Court for the District of Rhode Island

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***AMICI CURIAE* BRIEF OF THE STATES OF MAINE, CALIFORNIA, ALASKA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, IDAHO, ILLINOIS, IOWA, KANSAS, KENTUCKY, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, NEBRASKA, NEW HAMPSHIRE, NEW MEXICO, OREGON, RHODE ISLAND, TENNESSEE, TEXAS, UTAH, VERMONT, AND WASHINGTON SUPPORTING REVERSAL**

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INTEREST OF *AMICI CURIAE* STATES

Amici are the States of Maine, California, Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, Oregon, Rhode Island, Tennessee, Texas, Utah, Vermont, and Washington. The *Amici* States have strong interests, both as major payors for drug purchases, as well as antitrust enforcers in protecting fair competition in our pharmaceutical markets. Large portions of our state budgets pay for prescription drugs through State Medicaid and other public health programs. For instance, in 2013, the States spent $9.6 billion for Medicaid prescription drugs. U.S. Dep't of Health & Hum. Svcs., National Health Expenditures by Type of Service and Source of Funds: Calendar Year 1960-2013, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited April 28, 2015). That number is quickly rising. Katie Thomas, *Study Finds Broad Rise in Medication Use by Those Newly Joining Medicaid,* N.Y. TIMES (April 14, 2015), http://www.nytimes.com/2015/04/14/business/study-finds-broad-rise-in-medication-use-by-those-newly-joining-medicaid.html.

Nationally, in 2014, some $374 billion was spent on prescription drugs in the United States, 17% of $63 billion was paid by state and local governments.

Stuart Pfeifer, *Prescription drug spending jumps 13% to record $374 billion in 2014,* L.A. TIMES (April 14, 2015), http://www.latimes.com/business/la-fi-drug-costs-20150414-story.html; California Health Care Foundation, *Health Care Costs 101: Slow Growth: A New Trend?*, California Health Care Almanac, 10-11 (Sept. 2013), http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/H/PDF%20HealthCareCosts13.pdf.

At issue in this case is a pay-for-delay or "reverse payment" agreement, by which a branded pharmaceutical company gave consideration to its rivals in exchange for delayed competition in the context of settling a patent infringement lawsuit.[1] These agreements cause direct and substantial economic harm to the States and their residents by increasing drug prices and restricting consumer choice. Federal Trade Commission ("FTC") studies show that these agreements shield billions of dollars of drug sales from competition each year, resulting in unnecessarily high monopoly prices. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 2 (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-

[1] This type of settlement is called a reverse payment because it requires the patentee (plaintiff brand manufacturer) to pay the alleged infringer (defendant generic manufacturer), rather than the other way around. *F.T.C. v Actavis,* 133 S. Ct. 2223, 2227 (2013).

company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (finding these agreements cost consumers some $3.5 billion per year).

As major drug payors, the *Amici* States have a strong interest in preventing the imposition of those additional costs, and have standing to sue to protect their proprietary interest. *See, e.g.*, *Massachusetts v. E.P.A.,* 549 U.S. 497, 519 (2007). The States also have statutory standing under the Sherman Act and under their own, often unique, antitrust and competition statutes to protect the economic well-being of their residents. 15 U.S.C. § 15c; *see also California v. American Stores Co*., 495 U.S. 271, 282 (1990); *Georgia v. Pennsylvania R.R.*, 324 U.S. 439, 447 (1945).

Acting as antitrust enforcers, States have previously challenged reverse payment agreements to protect their consumers from the artificially high drug prices that result from those agreements. For example, the State of California paired with the FTC in bringing the action underlying the Supreme Court's recent opinion in *F.T.C. v. Actavis*, holding that the Sherman Act reached pay-for-delay agreements. The proper interpretation of that case is the crux of the *Amici* States' dispute with the decision below. *F.T.C. v. Actavis*, 133 S. Ct. 2223 (2013)

("*Actavis*").[2] Many of the States have also appeared as parties or *amicus curiae* in numerous proceedings in different venues across the nation challenging these agreements. *See, e.g.*, Brief of the States of California, *et al.* as *Amici Curiae* Supporting Petitioner, *Louisiana Wholesale Drug Co. v. Bayer AG* (U.S. Sup. Ct. Jan. 7, 2011) Ct. No. 10-762; Brief of 34 State Attorneys General as *Amici Curiae* Supporting Petitioner, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG,* 604 F.3d 98 (2d Cir. 2010); Brief of Attorneys General as *Amici Curiae, F.T.C. v. Watson Pharmaceuticals, Inc.* (U.S. Sup. Ct. 2013) No. 12-416; Brief for the States of Mississippi, *et al.* as *Amici Curiae*, *King Drug Co. and Louisiana Wholesale Drug Co. v. Smithkline Beecham Corp.*, *et al.* (3rd Cir. 2014) Case No. 14-1243; *see also*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005).

ARGUMENT

Reverse payment drug patent settlements that result in valuable consideration flowing to the would-be generic competitor in exchange for delay of the launch of its generic version must give rise to antitrust scrutiny whether that

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[2] The case was originally titled *FTC and the State of California v. Watson Pharmaceuticals, Inc., et al.*, and filed in C.D. Cal. (Case No. CV-09-00598 AHM (PLAx)). In January 2009, the case was transferred to Georgia over the jurisdictional objections of the State of California, after which the State entered a voluntary dismissal.

consideration is a cash pay-off or some other thing of value. Such is the only logical conclusion to be drawn from the Supreme Court's holding in *Actavis*, longstanding antitrust jurisprudence and basic principles of payment and consideration.

In *Actavis*, the U.S. Supreme Court focused on "genuine adverse effects on competition" that flow from reverse payment agreements. *Actavis*, 133 S. Ct. at 2234, 2244 (internal quotations omitted). The anticompetitive effects of reverse payment agreements are the same regardless of the form of payment. Consistent with antitrust jurisprudence generally, the *Actavis* analysis focuses not on the form of the payment, but rather on the payment's economic effect and resulting consumer harm—the very bedrock of antitrust law. *See, e.g.*, *Eastman Kodak v. Image Technical Serv. Inc.*, 504 U.S. 451, 466-67 (1992) ("[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law."); *E. Scientific Co. v. Wild Heerbrugg Instruments, Inc.*, 572 F.2d 883, 885-86 (1st Cir. 1978) (looking to "substantive economic effect" rather than form of retail price restraints to determine whether agreements violated the Sherman Act); *see also Actavis*, 133 S. Ct. at 2238 ("The point of antitrust law is to encourage competitive markets to promote consumer welfare.") (Roberts, C.J., dissenting). The district court's unsupportable narrowing of *Actavis*

to cash-only payments is at odds with *Actavis* and the longstanding touchstones of antitrust law.

The language, spirit, and facts of *Actavis* contradict such a restriction. Not only is the *Actavis* decision replete with language indicative of the significance of valuable consideration, regardless of the form, but the very reverse payment agreements reviewed by the *Actavis* Court were not direct cash payments, but rather agreements by the brand manufacturer to overpay the would-be generic competitors for other services. Moreover, neither antitrust law, nor other areas of substantive law, nor common usage limit "payment" to cash, excluding other forms of consideration. Finally, no matter how the generic producer is paid, the substance and result of the transaction are the same. In all, delayed competition, however procured, results in the same significant anticompetitive effects and harm to consumers.

I. NOTHING IN *ACTAVIS* SUPPORTS RESTRICTING ITS MANDATE TO CASH PAYMENT FORMS.

The lower court wrongly asserted that the Supreme Court in *Actavis* "fixates on the one form of consideration that was at issue in that case: cash." *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 189 (D. R.I. 2014). That attribution is readily invalidated by the facts of *Actavis*, as well as the language of the decision, which also uses non-cash terms and uses cash to refer to value. *See, e.g.*, *Actavis,* 133 S. Ct at 2234 (noting Congress' condemnation of reverse

payment settlements and quoting Sen. Hatch: "It was and is very clear that the [Hatch–Waxman Act] was not designed to allow deals between brand and generic companies to delay competition." 148 Cong. Rec. 14437 (2002) (internal quotations omitted)). The Court referred to "reverse payment settlements—*e.g.,* in which A, the plaintiff, pays money to defendant B," suggesting by use of "*e.g.*" (rather than "*i.e.*") that this scenario is simply an example of a reverse payment settlement and that there are others. *Id.* at 2233*; see also In re Lamictal Direct Purchaser Antitrust Litigation,* 18 F. Supp. 3d 560, 568 (D. N.J. 2014).

Most importantly, *Actavis* itself did not involve a direct cash payment as a *quid pro quo* for the delayed generic entry. Rather, the companies in *Actavis* entered into a series of sweetheart side deals in which the branded company gave additional consideration for the generics' agreement to delay entry. As the Court noted, "[t]he companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value." *Actavis,* 133 S. Ct. at 2229, 2230. Rather than focus on the form, the Court focused on the substance of the transaction, allowing the settlement to be reviewed as a potentially illegal agreement where "[t]he FTC alleges that *in substance*, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages." *Id.* at 2231 (emphasis added).

The *Loestrin* agreements, like those in *Actavis,* did not involve an explicit pay-off to delay generic entry—no check was written by Warner Chilcott with "for delayed generic entry" on the memo line. In recent years, delayed generic entry agreements have evolved into complex contracts, using highly structured and opaque forms of consideration so that pure cash reverse payment agreements are now considered "quaint" or a "relic."[3] *In re Cipro I & II*, No. S198616, 2015 WL 2125291, at *27, n.11 (Cal. May 7, 2015) ("To some extent, the settlement agreement challenged here is a relic. Cash reverse payments were not uncommon in the 1990s, but shortly thereafter brands and generics began using a wide range of other forms of consideration to accomplish reverse payment.") (citing C. Scott Hemphill, *The Aggregate Approach to Antitrust: Using New Data and Agency Rules to Preserve Drug Competition,* 109 Colum. L. Rev. 629, 647-658 (2009)); Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach,* 41 Rutgers L.J. 83, 98 (2009) ("Such [cash] settlements, which appear quaint in contrast to today's sophisticated version of three-drug monte, are no longer observed in today's marketplace.").

One common form of consideration is a promise by a branded pharmaceutical company not to introduce its own generic version of a drug during

[3] Even the court below recognized the growing complexity of these agreements. *In re Loestrin 24 FE Antitrust Litig.,* 45 F.Supp.3d at 193, 194.

the 180-day period of marketing exclusivity granted to the first generic manufacturer to file an Abbreviated New Drug Application for approval to market a bioequivalent to the brand ("first-filer"). *See* 21 U.S.C. § 355(j)(5)(B)(iv). An "authorized generic" drug is chemically identical to its brand-name counterpart, but is sold by the brand manufacturer as a generic under the same regulatory approval as the branded product. Promises by the brand-name manufacturer not to launch its own authorized generic when the first generic begins to compete are generally called "no authorized generic agreements" or "no-AG agreements." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, 145 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012*, 1-2 (2013), http://www.ftc.gov/os/2013/01/130117mmareport.pdf (study found that no-authorized generic agreements have steadily increased over the past few years). Since the competition that would otherwise be created by the "authorized (*i.e.* brand manufacturer's) generic" dramatically reduces the first-filer generic manufacturer's revenues by 40% to 52% on average, a no-AG promise

provides substantial economic value to the generic manufacturer at great expense to consumers. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at iii. The majority in *Actavis* recognizes that significant economic benefit in noting that the 180-day generic exclusivity period could be worth several hundred million dollars to the first generic producer. *Actavis*, 133 S. Ct. at 2229, 2235.

Among the generic pay-offs at issue in this case is just such an agreement. The no-AG agreement to Watson,[4] and the other non-cash consideration Warner Chilcott gave to both generics (Watson and Lupin) to delay launch of generic Loestrin 24,[5] are simply variations of the non-cash, unlawful reverse payment agreements specifically addressed in *Actavis*.

Seven of the eight other federal district courts evaluating whether the rule of *Actavis* requires cash consideration to constitute a potentially illegal reverse payment have concluded that *Actavis* was not limited to cash payment agreements by its facts, language or spirit.[6] As noted by the U.S. District Court for the District

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[4] The settlement was originally with Watson, now owned by Actavis.

[5] Warner Chilcott also agreed to provide additional non-cash benefits, namely to cross promote and sell two drugs owned by Watson, and entered financially beneficial cross licensing and distribution agreements on other drugs owned by Lupin, a second would-be generic manufacturer of Loestrin. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 186-187.

[6] The only case to hold the opposite, besides the district court below, is *In re Lamictal Direct Purchaser Antitrust Litig.,* 18 F.Supp.3d 560 (D.N.J. 2014).

of Massachussets in *In re Nexium Antitrust Litigation*, "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment," and "[a]dopting a broader interpretation of the word 'payment' . . . serves the purpose of aligning the law with modern-day realities." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013); *see also Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709 (E.D. Pa. 2014) (also involving Nexium) ("reverse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments").

The U.S. District Court for the Eastern District of Pennsylvania in *In re Niaspan Antitrust Litigation* also affirmed that *Actavis* did not require cash, noting that multiple "courts have refused to limit the term 'payment' to an exchange of cash in numerous areas of the law." *In re Niaspan Antitrust Litig.*, 42 F.Supp.3d 735, 751 (E.D. Penn. 2014) ("[T]he term 'reverse payment' is not limited to a cash payment."). The *Niaspan* court also observed that such a limited reading of *Actavis* would be "particularly anomalous in the context of antitrust law, in which 'economic realities rather than a formalistic approach must govern.'" *Id.* (quoting *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005)).

In *Effexor XR Antitrust Litigation*, Judge Sheridan noted that the "common use of the term payment is described as something given to discharge a debt or

obligation and does not require the payment to be in the form of money." *In re Effexor XR Antitrust Litigation*, No. 11-cv-5479, 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014). Further, "a non-monetary payment includes something of value that can be converted to a concrete, tangible, or defined amount which yields a reliable estimate of a monetary payment." *Id.*

The U.S. District Court for the District of Connecticut in *In re Aggrenox Antitrust Litigation* cautioned that if antitrust scrutiny could be avoided by making reverse payments in gold bullion rather than dollars, then "*Actavis* stands for nothing but an arbitrary restriction on the form such payments can take," an interpretation that would "cabin its reasoning to the point of meaninglessness." *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516 (SRU), 2015 WL 1311352, at *12 (D. Conn. March 23, 2015); *see also In re Lipitor Antitrust Litig.*, No. 3:12–cv–2389 (PGS), 2013 WL 4780496, at *26 (D.N.J. Sept. 5, 2013) ("[N]othing in *Actavis* strictly requires that the payment be in the form of money . . . .").

The court below wrongly posits that the *Actavis* factors for determining anticompetitive effects can only "be reasonably measured when the reverse payment is a cash payment; a non-cash settlement, particularly one that is multifaceted and complex (like the arrangement here), is almost impossible to measure against these five factors." *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 191. The district court in *United Food and Commercial Workers Local*

1776 v. Teikoku Pharma USA, Inc. (*Lidoderm)* found no such difficulty with non-cash pay-offs, specifically determining that a " no-authorized-generic term can constitute payment," that there were no cases to the contrary, and that the court had abundant means to affix a monetary value to such agreements. *United Food and Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.,* No. 14-md-02521-WHO, 2014 WL 6465235, at *10 - *12 (N.D. Cal. Nov. 17, 2014) ("However, not all non-monetary payments are impossible to value. There are many plausible methods by which plaintiffs may calculate the value of non-monetary terms."). The court in *Lidoderm* concluded that calculating the value of a product transfer agreement was "straightforward," and that the plaintiffs' valuation of a no-authorized generic term in the agreement at issue was "plausible."[7] *Id.* at *12.

Finally, in addition to these multiple federal district courts, the California Supreme Court also recently held that *Actavis* did not require that only payments made in cash are potentially violative of antitrust laws. *In re Cipro I & II,* at *1. In determining whether the Cartwright Act, California's antitrust statute, reached reverse payment agreements, the court explained in a well-reasoned opinion that reverse payment agreements were not limited to cash agreements since, shortly after the 1990's, branded and generic companies "began using a wide range of

[7] The plaintiffs relied on a study done by the FDA to show market capture rates and prices of first-filer generics and used those rates to project revenues for the generic. *Id.*

other forms of consideration to accomplish reverse payment[s].” *Id.* at *27, n.11 The Court further held that “creative variations” in the form of consideration should not result in “the purchase of freedom from competition.” *Id.*

As multiple courts have determined in recent years, *Actavis* does not support the narrow reading applied by the district court below. Reading *Actavis* to limit potentially illegal reverse payments to direct cash pay-offs narrows it to the point of practical irrelevance.

II. ANTITRUST LAW AND COMMON USAGE OF “PAYMENT” EMBRACE ALL FORMS OF CONSIDERATION.

The Supreme Court in *Actavis* reaffirmed that the ultimate goal of federal antitrust law is to protect consumers from harm caused by anticompetitive conduct. *Actavis*, 133 S. Ct. at 2236. In evaluating the competitive impact of a practice or agreement, the Supreme Court and this Court have consistently required that antitrust analysis “be based upon demonstrable economic effect rather than . . . upon formalistic line drawing.” *Eastman Kodak Co.*, 504 U.S. at 466-67 (“Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law.”); *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977); *E. Scientific Co.*, 572 F.2d at 885-86; *United States v. Delta Dental of Rhode Island*, 943 F. Supp. 172, 190 (D.R.I. 1996); *see also Toys “R” Us, Inc. v. F.T.C.*, 221 F.3d 928, 940 (7th Cir. 2000); *United States v. Apple Inc.*, 952 F. Supp. 2d 638, 688-89 (S.D.N.Y. 2013).

In reviewing a price-fixing scheme, antitrust law is indifferent to whether the scheme is accomplished through fixing cash, credit, or service components in competitors' agreements. *See*, *e.g.*, *Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 644 (1980) (competitors fixing credit terms constituted price-fixing); *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 24-25 (1979) (blanket licenses issued by defendants may constitute price-fixing under rule of reason); *see also United States v. Socony–Vacuum Oil Co.*, 310 U.S. 150, 224 (1940) ("[T]he machinery employed by a combination for price-fixing is immaterial. Under the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal per se."). Similarly, the Hart-Scott-Rodino Act's reporting requirement for merger transactions reaches all forms of compensation being exchanged, whether cash, real estate, contracts, stock options, product swaps or license rights. 15 U.S.C. § 18a. The central inquiry for antitrust analysis then is not the transaction's form, but rather its economic substance and the potential anticompetitive harm.

In this respect, antitrust law is no different from contract law and other subject areas that disregard the form of consideration or payment in prescribing an enforcement regime and remedy. Contract law holds that a promise for a promise or a promise for an act is an adequate form of consideration or payment. *Neuhoff*

v. Marvin Lumber and Cedar Co., 370 F.3d 197, 202 (1st Cir. 2004) ("Actions can constitute consideration when a promisee gives 'up something which immediately prior thereto the promisee was privileged to retain, or doing or refraining from doing something which he was then privileged not to do, or not to refrain from doing.'"); *F.D.I.C. v. O'Flahaven*, 857 F. Supp. 154, 162 (D.N.H. 1994) ("Consideration does not require that each side receive a direct, personal benefit.").

Beyond the antitrust and contract law context, case law and the federal statutes discuss "payment," or the concept of payment, in many forms. The Supreme Court has held that providing a plane ticket can constitute payment of wages. *American Foreign S.S. Co. v. Matise*, 423 U.S. 150, 159 (1975). Tax law assesses property and income taxes based upon different forms of value, and under 26 U.S.C. § 61(a)(1), one cannot evade payment of income taxes by using non-cash forms of compensation. I.R.S. Publication 525 (Jan. 15, 2015). The Supreme Court considers a tax credit the same as a cash payment. *Comm. for Public Education v. Nyquist*, 413 U.S. 756, 789-91 (1973); *see also* 11 U.S.C. § 548 (value of a transfer in bankruptcy). Forgiveness of debt is also considered receiving a payment of equivalent value. I.R.S. Publication 4681 (Jan. 15, 2015).

Thus, a "payment" in most, if not all, relevant areas of the law is not limited to cash. Likewise, the "payment" in a reverse payment settlement need not be cash, but includes any variety of consideration.

Asserting that "words have meaning," the lower court focused on *Actavis*' references to "cash consideration" in discussing reverse payment settlements, ignoring the heart of the *Actavis* holding that providing value in exchange for delayed entry warrants scrutiny under antitrust law. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 189. It also disregarded the common use of the term "payment" which Merriam Webster's Dictionary defines as "something that is given to someone in exchange for something else." *Payment Definition*, MERRIAM-WEBSTER.COM, http://www.merriam-webster.com/dictionary/payment (last visited June 2, 2015). Furthermore, Black's Law Dictionary expansively defines "payment" as "performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation." Black's Law Dictionary 1309 (10th ed. 2014). Nothing in *Actavis* abandons the common usage and understanding of the word "payment," and the law favors the ordinary meaning and usage of words. *See Carcieri v. Salazar*, 555 U.S. 379, 388-89 (2009) (consulting Webster's and Black's dictionaries to understand the ordinary meaning of the word "now" in the Indian Reorganization Act).

The district court acknowledged that a non-cash reverse payment settlement could harm competition—the singular evil antitrust law seeks to remedy—yet disregarded those effects simply because the "payment" is not cash. *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d at 193, 194. Years of antitrust and other

substantive law addressing the implications of consideration and value exchanges, as well as common usage of the term ”payment,” teach us, however, that form does not trump substance and should not be the basis for evasion of antitrust liability.

III. A NO-AUTHORIZED GENERIC PLEDGE PROVIDES VALUE THAT IS WORTH MILLIONS OF DOLLARS AND CAUSES CONSUMERS TO OVERPAY FOR DRUGS.

While the first generic manufacturer for a drug is free from competition from other generic manufacturers for 180 days under the Hatch-Waxman Act, it is not legally protected from the brand name manufacturer's own authorized generic. 21 U.S.C. § 355(j)(5)(B)(iv); FDA, *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day*, at 2(June 2003) *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf. Thus, even though a no-authorized generic promise does not directly transfer cash from the branded company to a generic in exchange for delayed entry, it results in money in the generic's pocket and has the same adverse effect on competition.

In this case, the branded company, Warner Chilcott, allegedly secured an extended monopoly period for the branded Loestrin 24 FE birth control drug by providing Watson, one of the generics, with a very valuable agreement not to launch an authorized generic during Watson's 180-day exclusivity period, among

other consideration. *In re Loestrin 24 FE Antitrust Litig*., 45 F. Supp. 3d at 186. As the district court below itself recognized, "[b]ecause the price of a drug drops precipitously as more and more generics become available, this initial period of exclusivity can generate substantial profits for the first generic manufacturer." *Id.* at 185. Warner Chilcott's pledge not to compete during the 180-day period was worth tens of millions, if not hundreds of millions, of dollars, to the generic producer.[8] The no-AG agreement with Watson is clearly a transfer of tremendous value to the generic in exchange for its agreement to delay competition.

In all material respects, the challenged transactions, both the no-authorized generic pledge, and the cross promotion and licensing agreements, have the same economic structure and effect as the agreements in *Actavis*. The agreements provide something of value to the generics by including protection from competition *beyond* what the generics could have received by winning the patent litigation. In other words, companies are not merely compromising disputed patent rights; they are also making extraneous transfers of financial benefits, however

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[8] Public records show that sales of Loestrin 24 FE in 2012 were some $389 million. Warner Chilcott Pub. Ltd. Co., Annual Report (Form 10-K) (Dec. 31, 2012). Exclusivity for 180 days would transfer a substantial portion of those revenues to the first-filer generic manufacturer. Moreover, the lower court decision ignored the value conferred by the fact that Warner-Chilcott, the branded company, also agreed to co-promote and cross-license drugs from both Watson and Lupin in potentially lucrative side deals. *In re Loestrin 24 FE Antitrust Litig*., 45 F. Supp. 3d at 186-87.

disguised and obfuscated, to buy additional market exclusivity. As in *Actavis*, "the [patent] plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages." *Actavis,* 133 S. Ct. at 2231, 2233. Thus, the payment is not and cannot be justified as an incident of patent power but rather it is an agreement to buy protection from competition. Even if Watson had won the patent case underlying the dispute in the case at bar, the generic would not have been able to prevent the branded company from entering with an authorized generic during the 180-day exclusivity period without Warner Chilcott's no-AG consideration.

The settling of legitimate patent disputes is not at stake here. The allegedly infringing generic company can pay to settle a brand manufacturer's infringement claim, because it is a strong case or for nuisance litigation value, without risking antitrust scrutiny. Or, just like the patent litigants in *Actavis* could have, the companies in this matter could have settled the case by splitting the patent term "without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2237. Instead, they chose to divide the markets between themselves—providing to one another exclusive monopoly periods with generic and branded markets and dividing the monopoly profits—all at the expense of the consumers. The monopoly profits are shared, whether in the form of a direct check

from the brand company, or the opportunity for the generic to charge monopoly profits during a period it otherwise would not be able to.

Consumer harm from no-authorized generic pledges has been the subject of extensive studies by the Federal Trade Commission, the body mandated by Congress to study marketplace conduct and protect our consumers. 15 U.S.C. §§ 41-58. FTC studies demonstrate revenues of the first-filer generic manufacturer in the first 30 months following exclusivity are between 53 and 62 percent lower when facing competition from an authorized generic. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at iii. As the *Actavis* Court recognized, the 180-day exclusivity period for first filers is worth several hundred million dollars. *Actavis*, 133 S.Ct. at 2229. Erosion of that profit due to competition from the brand's own generic benefits consumers in the form of reduced prices. Conversely, the consumer is harmed from the extension of noncompetition and resulting higher prices, which result from the abeyance "payment" to the generic manufacturer by the brand name.

CONCLUSION

Throughout history, collusive market division agreements have been condemned and considered patently unlawful. See Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 2031 (3d ed. 2012) (Market division among competitors is considered perhaps the most pernicious form of anticompetitive

business behavior since it completely eliminates *all* competition between parties on *all* grounds.). While the patent element in reverse payment agreements may have allowed the agreements to evade enforcement for a period of time, that time is now over. *Actavis* restored antitrust oversight to this species of market division agreements, and superficial distinctions as to the manner of payment cannot justify departure from Supreme Court precedent. The lower court itself ultimately recognizes that its deference to cash is paradoxical and problematic given the intent of *Actavis*. *In re Loestrin 24 FE Antitrust Litig*., 45 F. Supp. 3d at 193-94. The decision below creating that paradox must be reversed to restore the vitality of *Actavis* in the First Circuit.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation, because it has 4,952 words, excluding the parts that Rule 32(a)(7)(B)(iii) exempts. *See* Fed. R. App. P. 28.1(e)(2)(B)(i). This brief complies with the typeface requirements, because it has 14 point Times New Roman font in Microsoft Word 2010. *See id.* 32(a)(5).

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CERTIFICATE OF SERVICE

I hereby certify that on June 16, 2015, I electronically filed the above *Amici Curiae* brief of the States of Maine, California, Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, Oregon, Rhode Island, Tennessee, Texas, Utah, Vermont, and Washington with the Clerk of the Court via the CM/ECF system, which will deliver notification of filing to all counsel of record.

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